CLAIMS

1. A mucoadhesive composition for solubilization of insoluble drugs comprising 4 ~ 90 % by weight of at least one monoglyceride compound and 0.01 ~ 90 % by weight of at least one oil.

2. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 1, additionally comprising 0.01 ~ 90 % by weight of at least one emulsifier.

3. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 1 or 2, wherein said monoglyceride compound is selected from a group consisting of a saturated or an unsaturated monoglyceride having 10 ~ 22 carbon atoms in the hydrocarbon chain.

4. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 3, wherein said monoglyceride compound is selected from monoolein, monopalmitolein, monomyristolein, monoelaidin, and monoerucin, or from a group consisting of the mixture of monoglycerides semi-synthesized from triglycerides of vegetable or animal oil.

5. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 1 or 2, wherein said oil is selected from a group consisting of triglyceride, iodized oil, vegetable oil and animal oil.

6. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 5, wherein said triglyceride is selected from a group consisting of saturated and unsaturated triglyceride having 2 ~ 20 carbon atoms in each hydrocarbon chain.

7. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 6, wherein said triglyceride is selected from a group consisting of triacetin, tributyrin, tricaproin, tricaprylin, tricaprin and triolein.

8. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 5, wherein said iodized oil is selected from a group consisting of Lipiodol, iodized poppy seed oil, Ethiodol and iodized soybean oil.

9. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 5, wherein said vegetable oil is selected from a group consisting of soybean oil, cottonseed oil, olive oil, poppyseed oil, linseed oil and sesame oil.

10. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 5, wherein said animal oil is selected from a group consisting of squalane and squalene.

11. The mucoadhesive composition for solubilization of insoluble drugs

according to Claim 2, wherein said emulsifier is selected from a phospholipid, a non-ionic surfactant, an anionic surfactant, a cationic surfactant and a bile acid.

12. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 11, wherein said phospholipid is selected from the group consisting of a phosphatidylcholine (PC) and its derivative, a phosphatidylethanolamine (PE) and its derivative, a phosphatidylserine (PS) and its derivative, and a polymeric lipid wherein a hydrophilic polymer is conjugated to the lipid headgroup.

13. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 11, wherein said non-ionic surfactant is selected from the group consisting of a poloxamer (Pluronic: polyoxyethylene-polyoxypropylene copolymer), a sorbitan ester (sorbitan esters; Span), a polyoxyethylene sorbitan (Tween) and a polyoxyethylene ether (Brij).

14. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 11, wherein said anionic surfactant is selected from the group consisting of a phosphatidylserine (PS) and its derivative, a phosphatidic acid (PA) and its derivative and sodium dodecyl sulfate (SDS).

15. The mucoadhesive composition for solubilization of insoluble drugs

according to Claim 11, wherein said cationic surfactant is selected from the group consisting of 1,2- dioleyl-3-trimethylammonium propane (DOTAP), dimethyldioctadecylammonium bromide (DDAB), N-[1-(1,2-dioleyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA), 1,2-dioleyl-3-ethylphosphocholic acid (DOEPC) and 3β-[N-[(N',N'-dimethylamino)ethan]carbamoyl]cholesterol (DC-Chol).

16. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 11, wherein said bile acid is selected from the group consisting of cholic acid, its salt and derivatives; deoxycholic acid, its salt and derivatives; chenocholic acid, its salt and derivatives; and lithocholic acid, its salt and derivatives.

17. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 1 or 2, additionally comprising 0.01 ~ 5 % by weight of other additives.

18. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 17, wherein said other additives are selected from the group consisting of Cremophor, tocopherol, tocopherol acetate, fatty acids, fatty acid esters, fatty acid alcohols, alcohols and polyols.

19. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 18, wherein said alcohols are selected from the group consisting of methanol, ethanol, propanol and isopropanol.

20. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 18, wherein said polyols are selected from the group consisting of ethyleneglycol, propyleneglycol and polyethyleneglycol.

21. A preparation method of mucoadhesive composition for solubilization of insoluble drugs according to Claim 1, wherein said method comprises the step of preparing a viscous liquid by solubilizing at least 4 ~ 90 % by weight of at least one monoglyceride compound in 0.01 ~ 90 % by weight of at least one oil.

22. The preparation method according to Claim 21, wherein the said mixture is heated to 50 °C to speed up the solubilization process.

23. A preparation method of mucoadhesive composition for solubilization of insoluble drugs according to Claim 2, wherein said method comprises the step of preparing a viscous liquid by mixing at least 4 ~ 90 % by weight of at least one monoglyceride compound and 0.01 ~ 90 % by weight of at least one oil with 0.01 ~ 90 % by weight of at least one emulsifier.

24. The preparation method according to Claim 23 wherein the said mixture is heated to 50 °C to speed up the solubilization process.

25. The preparation method according to Claim 23 wherein the said mixture

is sonicated in a bath type sonicator to speed up the solubilization process.

26. A mucoadhesive formulation for solubilization of insoluble drugs comprising 4 ~ 90 % by weight of at least one monoglyceride compound, 0.01 ~ 90 % by weight of at least one oil and 0.01 ~ 20 % by weight of at least one insoluble drug.

27. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26, additionally containing 0.01 ~ 90 % by weight of at least one emulsifier.

28. The mucoadhesive formulation for solubilization of insoluble drugs according to Claims 26 or Claim 27, herein said monoglyceride compound is selected from monoolein, monopalmitolein, monomyristolein, monoelaidin, and monoerucin, or from a group consisting of the mixture of monoglycerides semi-synthesized from triglycerides of vegetable or animal oil.

29. The mucoadhesive formulation for solubilization of insoluble drugs according to Claims 26 or Claim 27, wherein said oil is selected from a group consisting of triglyceride, iodized oil, vegetable oil and animal oil.

30. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 29, wherein said triglyceride is selected from a group consisting of saturated and unsaturated triglyceride having 2 ~ 20 carbon

atoms in each hydrocarbon chain.

31. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 30, wherein said triglyceride is selected from a group consisting of triacetin, tributyrin, tricaproin, tricaprylin, tricaprin and triolein.

32. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 29, wherein said iodized oil is selected from a group consisting of Lipiodol, iodized poppy seed oil, Ethiodol and iodized soybean oil.

33. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 29, wherein said vegetable oil is selected from a group consisting of soybean oil, cottonseed oil, olive oil, poppyseed oil, linseed oil and sesame oil.

34. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 29, wherein said animal oil is selected from a group consisting of squalane and squalene.

35. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 27, wherein said emulsifier is selected from a phospholipid, a non-ionic surfactant, an anionic surfactant, a cationic surfactant and a bile acid.

36. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 35, wherein said phospholipid is selected from the group consisting of a phosphatidylcholine (PC) and its derivative, a phosphatidylethanolamine (PE) and its derivative, a phosphatidylserine (PS) and its derivative and a polymeric lipid wherein a hydrophilic polymer is conjugated to the lipid headgroup.

37. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 35, wherein said non-ionic surfactant is selected from the group consisting of a poloxamer (Pluronic: polyoxyethylene-polyoxypropylene copolymer), a sorbitan ester (sorbitan esters; Span), a polyoxyethylene sorbitan (Tween) and a polyoxyethylene ether (Brij).

38. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 35, wherein said anionic surfactant is selected from the group consisting of a phosphatidylserine (PS) and its derivative, a phosphatidic acid (PA) and its derivative or sodium dodecyl sulfate (SDS).

39. The mucoadhesive composition for solubilization of insoluble drugs according to Claim 35, wherein said cationic surfactant is selected from the group consisting of 1,2- dioleyl-3-trimethylammonium propane (DOTAP), dimethyldioctadecylammonium bromide (DDAB), N-[1-(1,2-dioleyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA),

1,2-dioleyl-3-ethylphosphocholic acid (DOEPC) and 3β-[N-[(N',N'-dimethylamino)ethan]carbamoyl]cholesterol (DC-Chol).

40. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 35, wherein said bile acid is selected from the group consisting of cholic acid, its salt and derivatives; deoxycholic acid, its salt and derivatives; chenocholic acid, its salt and derivatives; and lithocholic acid, its salt and derivatives.

41. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26 or Claim 27, wherein said bioactive compound is selected from the group consisting of antivirals, steroidal anti-inflammatory drugs (SAID), non-steroidal anti-inflammatory drugs (NSAID), antibiotics, antifungals, vitamins, hormones, prostaglandins, prostacyclins, anticancer drugs, antimetabolitic drugs, miotics, cholinergics, adrenergic antagonists, anticonvulsants, antianxiety agents, major tranquilizers, antidepressants, anesthetics, analgesics, anabolic steroids, estrogens, progesterones, glycosaminoglycans, polynucleotides, immunosuppressants and immunostimulants.

42. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26 or 27, additionally comprising 0.01 ~ 5 % by weight of other additives.

43. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 42, wherein said other additives are selected from the group consisting of Cremophor, tocopherol, tocopherol acetate, fatty acids, fatty acid esters, fatty acid alcohols, alcohols and polyols.

44. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 43, wherein said alcohols are selected from the group consisting of methanol, ethanol, propanol and isopropanol.

45. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 43, wherein said polyols are selected from the group consisting of ethyleneglycol, propyleneglycol and polyethyleneglycol.

46. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26 or 27, wherein the administration route is selected from oral administration, buccal administration, mucosal administration, intranasal administration, intraperitoneal administration, subcutaneous injection, intramuscular injection, transdermal administration and intratumoral injection.

47. The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26 or 27 existing in liquid or semi-solid form.

48. A method of preparing the mucoadhesive formulation for solubilization of

insoluble drugs according to Claim 26, wherein said method comprises the steps of:

1) solubilizing 4 ~ 90 % by weight of at least one monoglyceride compound in 0.01 ~ 90 % by weight of at least one oil (step 1); and

2) solubilizing completely 0.01 ~ 20 % by weight of at least one insoluble drug in said mixture in step (1) by stirring (step 2).

49. The preparation method according to Claim 48 wherein the said mixture is heated to 50 °C in step (1) to speed up the solubilization process.

50. The preparation method according to Claim 48 wherein the said mixture is sonicated in a bath type sonicator in step (2) to speed up the solubilization process.

51. A preparation method of mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26, wherein said method comprises the step of preparing a homogenous liquid by mixing completely at least one monoglyceride compound, at least one oil and insoluble drug.

52. The preparation method according to Claim 51 wherein the said mixture is heated to 50 °C and sonicated in a bath type sonicator to speed up the solubilization process.

53. A method of preparing the mucoadhesive formulation for solubilization of insoluble drugs according to Claim 27, wherein said method comprises the steps of:

1) preparing a viscous liquid by mixing completely 4 ~ 90 % by weight of at least one monoglyceride compound, 0.01 ~ 90 % by weight of at least one oil and 0.01 ~ 90 % of at least one emulsifier (step 1); and

2) preparing a viscous liquid by mixing completely insoluble drug with said liquid in step (1) (step 2).

54. The preparation method according to Claim 53 wherein the said liquid is heated to 50 °C in step (1) to speed up the solubilization process.

55. The preparation method according to Claim 53 wherein the said liquid is heated to 50 °C in step (2) to speed up the solubilization process.

56. The preparation method according to Claim 53 wherein the said liquid is sonicated in a bath type sonicator in step (2) to speed up the solubilization process.

57. A method of preparing the mucoadhesive formulation for solubilization of insoluble drugs according to Claim 27, wherein said method comprises the steps of:

1) preparing oily liquid containing drug by solubilizing completely 0.01 ~ 20 % by weight of insoluble drug in 0.01 ~ 90 % by weight of at least one oil (step 1); and

2) preparing a homogeneous liquid by mixing completely said liquid in step (1) with 4 ~ 90 % by weight of at least one monoglyceride compound and 0.01 ~ 90 % of at least one emulsifier (step 2).

58. The preparation method according to Claim 57, wherein the said liquid is heated to 50 °C and sonicated in a bath type sonicator in step (2) to speed up the solubilization process.